

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
ACTING AS THE DESIGNATED/ELECTED OFFICE

In re: Patent application of: Karl MULLIGAN
Derek McCORMICK
Patrick JOHNSTON

Application No: 10/579,168
(International Application No: PCT/GB2004/004788)
Filed: (International Application: 15 November 2004 (15.11.2004))
For: CANCER DIAGNOSIS AND THERAPY

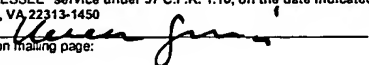
MAIL STOP PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

ATTN: Ms. Vonda M. Wallace:

**RESPONSE TO NOTIFICATION TO COMPLY WITH REQUIREMENTS
FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE
AND/OR AMINO ACID SEQUENCE DISCLOSURES**

This is in response to the NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) ("Notification"), mailed from the U.S. Patent and Trademark Office on December 14, 2006, to which a response is due February 14, 2007. A copy of the Notification is enclosed herewith. No fee is believed due to support this submission. However, should any fee is due, please charge the same to Deposit Account No. 50-0573.

The Notification alleges that the Applicants failed to comply with 37 CFR 1.821-1.825, and that Applicants are required to submit an initial computer readable form (CRF) copy of the "Sequence Listing", an initial paper copy of the "Sequence Listing", an amendment directing its entry into the specification, and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper) Sequence Listing.

CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.10	
EXPRESS MAIL Mailing Label Number:	EV299883790US
Date of Deposit:	January 17, 2007
I hereby certify that this correspondence, along with any paper referred to as being attached or enclosed, and/or fee, is being deposited with the United States Postal Service, "EXPRESS MAIL-POST OFFICE TO ADDRESSEE" service under 37 C.F.R. 1.10, on the date indicated above, and addressed to: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450	
Signature of person mailing page: 	
KAREN M. SPINA Type or print name of person	

It is respectfully submitted that the issuance of the Notification is improper for the following reasons:

On September 7, 2006, Applicants submitted a initial computer readable form (CRF) of the Sequence Listing as required under to 37 CFR 1.825(e), along with a STATEMENT TO SUPPORT FILING AND SUBMISSION IN ACCORDANCE with 37 CFR §§ 1.821-1.825.

A written (on paper) copy of the Sequence Listing as required under 37 CFR 1.821(c) was contained in the international application as originally filed. Thus, neither an initial written (on paper) copy of the Sequence Listing, nor an amendment directing entry of the Sequence Listing into the specification upon entry into the US national stage, are required.

The Postcard Receipt, with a PCT/PTO date stamp of "IAP6 Rec'd PCT/PTO 07 SEP 2006", was received in the offices of the Applicants' attorney on September 18, 2006, indicating that all of the enclosures identified on the Postcard Receipt were in fact received by the USPTO on September 7, 2006, as follows:

- (1) Transmittal Letter PTO Form 1390;
- (2) copy of International Search Report and Written Opinion;
- (3) copy of IPRP;
- (4) Information Disclosure Statement/PTO-1449 including copies of certain cited references;
- (5) Sequence Listing diskette; and
- (6) Statement to Support Filing and Submission in Accordance with 37 CFR 1.821-1.825.

A copy of the date-stamped Postcard Receipt is attached hereto as **EXHIBIT A**.

All of the items mailed on September 7, 2006 and identified on the Postcard Receipt were included in a single package, and mailed via Express Mail to Mail Stop PCT, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450. A *courtesy* copy of the enclosures as filed on September 7, 2006 is attached hereto as **EXHIBIT B**.

It is respectfully submitted that Applicant fulfilled the U.S. national stage requirements as of September 7, 2006. The submission of the courtesy copy should not be construed as an admission by Applicants that national stage requirements have not been met.

Issuance of a NOTICE OF ACCEPTANCE UNDER 35 U.S.C. 371 is earnestly solicited.

Respectfully submitted,

Karl MULLIGAN *et al.*

BY 

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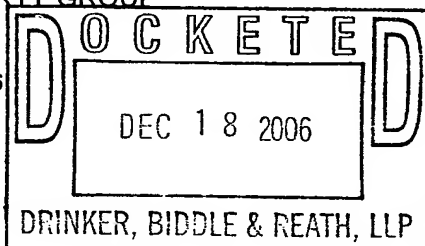
UNITED STATES PATENT AND TRADEMARK OFFICE

224/24
UNITED STATES DEPARTMENT OF COMMERCE
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www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/579,168	Karl Mulligan	36290-0409-00-US

23973

DRINKER BIDDLE & REATH
ATTN: INTELLECTUAL PROPERTY GROUP
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18TH AND CHERRY STREETS
PHILADELPHIA, PA 19103-6996



Date Mailed: 12/14/2006

INTERNATIONAL APPLICATION NO.	
PCT/GB04/04788	
I.A. FILING DATE	PRIORITY DATE
11/15/2004	11/14/2003

CONFIRMATION NO. 8905

371 FORMALITIES LETTER



OC000000021571991

NOTIFICATION TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant is given **TWO MONTHS FROM THE DATE OF THIS NOTICE** within which to file the items indicated below to avoid abandonment. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

- This application clearly fails to comply with the requirements of 37 CFR 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing", an initial paper or compact disc copy of the "Sequence Listing", as well as an amendment specifically directing its entry into the application. Applicant must also provide a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.
- A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages: If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:

COPY

- For Rules Interpretation, call (571) 272-0951
- For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patentin Software Program Help @ ebc@uspto.gov

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at 1-866-217-9197 or visit our website at <http://www.uspto.gov/ebc>.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

VONDA M WALLACE

Telephone: (703) 308-9140 EXT 225

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/579,168	PCT/GB04/04788	36290-0409-00-US

FORM PCT/DO/EO/922 (371 Formalities Notice)

SEP 21 2006

DRINKER, BIDDLE & REATH, LLP

Attorney Doc. No. 36290-0409-00-US
Re: Patent Application of MULLIGAN et al; US App. No. 10/579,168
Filed: (I.A. 15 NOV 2004)
For: CANCER DIAGNOSIS AND THERAPY

The U.S. Patent Office acknowledges and has stamped hereon the date of receipt of the attached paper(s):

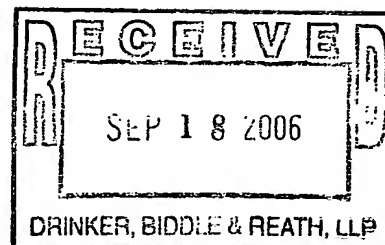
(1) TNS LTR PTO Form 1390; (2) copy of International Search Report and Written Opinion; (3) copy of IPRP; (4) Information Disclosure Statement/PTO-1449 including copies of certain cited references; (5) Sequence Listing Diskette; (6) Statement to Support Filing and submission in Accordance with 37 CFR 1.821-1.825;

Certificate of Mailing § 1.10: September 7, 2006

Express Mail Label No.

EV320483827US

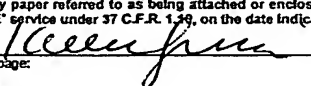
IAP6 Rec'd PCT/PTO 07 SEP 2006



TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER 36290-0409-00-US U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/579,168
INTERNATIONAL APPLICATION NO. PCT/GB2004/004788	INTERNATIONAL FILING DATE 15 NOV 2004 (15.11.2004)	PRIORITY DATE CLAIMED 14 NOV 2003 (14.11.2003)
TITLE OF INVENTION CANCER DIAGNOSIS AND THERAPY		
APPLICANT(S) FOR DO/EO/US Karl MULLIGAN; Derek McCORMICK; Patrick JOHNSTON		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<p>1. <input type="checkbox"/> This is a FIRST submission of items concerning a submission under 35 U.S.C. 371.</p> <p>2. <input checked="" type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371.</p> <p>3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</p> <p>4. <input type="checkbox"/> The US has been elected (Article 31).</p> <p>5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))</p> <p style="margin-left: 40px;">a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</p> <p style="margin-left: 40px;">b. <input type="checkbox"/> has been communicated by the International Bureau.</p> <p style="margin-left: 40px;">c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</p> <p>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).</p> <p style="margin-left: 40px;">a. <input type="checkbox"/> is attached hereto.</p> <p style="margin-left: 40px;">b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</p> <p>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))</p> <p style="margin-left: 40px;">a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</p> <p style="margin-left: 40px;">b. <input type="checkbox"/> have been communicated by the International Bureau.</p> <p style="margin-left: 40px;">c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</p> <p style="margin-left: 40px;">d. <input type="checkbox"/> have not been made and will not be made.</p> <p>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p> <p>Items 11 to 20 below concern document(s) or information included:</p> <p>11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input type="checkbox"/> A preliminary amendment.</p> <p>14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</p> <p>15. <input type="checkbox"/> A substitute specification.</p> <p>16. <input type="checkbox"/> A power of attorney and/or change of address letter.</p> <p>17. <input checked="" type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.</p> <p>18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).</p> <p>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</p>		

COPY

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.** Page 1 of 3

EXPRESS MAIL Mailing Label Number: Date of Deposit: September 7, 2006		CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.10 EV320483827US September 7, 2006	
I hereby certify that this correspondence, along with any paper referred to as being attached or enclosed, and/or fee, is being deposited with the United States Postal Service, "EXPRESS MAIL-POST OFFICE TO ADDRESSEE" service under 37 C.F.R. 1.19, on the date indicated above, and addressed to: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450			
Signature of person mailing page: KAREN M. SPINA			
Type or print name of person			

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.


U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/579,168		INTERNATIONAL APPLICATION NO. PCT/GB2004/004788		ATTORNEY'S DOCKET NUMBER 36290-0409-00-US	
20. Other items or information: copy of International Search Report and Written Opinion; copy of IPRP; Statement to Support Filing and Submission in Accordance with 37 CFR 1.821-1.825; postcard receipt					
The following fees have been submitted				CALCULATIONS PTO USE ONLY	
21. <input type="checkbox"/> Basic national fee (37 CFR 1.492(a))..... \$300				\$	
22. <input type="checkbox"/> Examination fee (37 CFR 1.492(c))				\$	
If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0 All other situations..... \$200				\$	
23. <input type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... \$100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB..... \$400 All other situations..... \$500				\$	
TOTAL OF 21, 22 and 23 =					
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) in an electronic medium or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
- 100 =	/50 =		x \$250	\$	
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	- 20 =		x \$ 50	\$	
Independent claims	- 3 =		x \$200	\$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$360	\$	
TOTAL OF ABOVE CALCULATIONS =				\$	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.					
SUBTOTAL =				\$	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).				\$	
TOTAL NATIONAL FEE =				\$	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				\$	
TOTAL FEES ENCLOSED =				\$	- 0 -
				Amount to be refunded:	\$
				Amount to be charged	\$

- a. ☐ A check in the amount of \$ _____ to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees.
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0573. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

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SIGNATURE
DANIEL A. MONACO
NAME
30,480
REGISTRATION NUMBER

Customer No. 23973